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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,167	10/24/2001	Erica J. Pascal	50018A	4256

22847 7590 10/20/2004

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,167

Applicant(s)

PASCAL ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17,21-29,50,51,58,59,66 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-7,10-12,15-17,22,24-27,50,51,58,59,66 and 67 is/are allowed.
- 6) ☒ Claim(s) 8,9,13,14,21,23,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>4/7/04</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

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DETAILED ACTION

This office action is in response to an amendment filed 7/26/04. Claims 1, 18-20, 30-49, 52-57, 60-65 and 68-97 have been cancelled. Claims 2, 4, 21-25, 51, 59 and 66-67 have been amended. Claims 2-17, 21-29, 50, 51, 58, 59, 66 and 67 are pending.

Response to Amendment

Any rejection of record in the previous action not addressed in this office action is withdrawn. There are new grounds of rejection herein that were not necessitated by applicants' amendment and therefore, this action is not final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 9, 13, 14, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection.**

Claims 8, 9, 13, 14, 28 and 29 are vague and indefinite in that the metes and bounds of "stringent conditions" are unclear. The claimed conditions are ambiguous as the specification teaches that stringent can be one of a variety of conditions i.e. will hybridize to its target but to no other sequences, 5 degrees lower than melting temperature (see e.g. page 62, paragraph 3). But the claims do not define which of these conditions are appropriate to identify the recited sequences. Therefore, the claimed nucleotide sequences are not defined.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8, 9, 13, 14, 28 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This is a new rejection.**

Applicants claim a genus of receptor cassettes comprising a nucleic acid sequence the complement of which hybridizes under stringent conditions to SEQ ID NO: 120 or 104.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus.

Applicants' invention is drawn to receptor cassettes that encode chimeric receptors comprised of DNA binding domains, hinge domains, ligand binding domains and transactivation domains from a variety of sources. For example, SEQ ID NO: 120 comprises the GAL4 DNA binding domain, *Manduca sexta* hinge domain and *Ostrinia nubilalis* ligand binding domain while SEQ ID NO: 104 comprises the GAL4 DNA binding domain, *Manduca Sexta* hinge and ligand binding domain and VP16 transactivation domain. Applicants claim a genus of receptor cassettes that comprise nucleic acid sequences the complement of which hybridizes to SEQ ID

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NO: 120 or 104 under “stringent conditions”. By recitation of sequences isolated following hybridization under “stringent conditions” to the complement of SEQ ID NO: 120 and 104, the relationship between structure and function is unclear. The specification only teaches that stringent can be one of a variety of conditions i.e. will hybridize to its target but to no other sequences, 5 degrees lower than melting temperature (see e.g. page 62, paragraph 3). But the claims do not define which of these conditions are appropriate to identify the recited sequences. Therefore, applicants have not reduced to practice the instant invention as neither stringent conditions nor the claimed nucleotide sequences are defined. Furthermore, the specification fails to either convey the relevant identifying characteristics of the recited nucleic acids or provide a description of the nucleic acids such that their structural requirements can be envisioned. Given the unknown nature of the “stringent conditions” and hence the widely divergent nature of the nucleic acid molecules that would be isolated upon hybridization under “stringent conditions” and the uncertainty of the activity of any nucleic acid sequence, it must be considered that any of receptor cassette must be empirically determined. In an unpredictable art, the disclosure of one example in no examples would represent to the skilled artisan that applicants were not in possession of claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

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international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Palli et al, US 2002/0119521 A1, see entire document. **This is a new rejection.**

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Palli et al teach construction of a novel ecdysone receptor based inducible gene expression system in which chimeric ecdysone receptors are expressed from promoters on plasmids or vectors (see e.g. paragraph 0123). Figures 4 and 7 teach a chimeric receptor comprising an activation domain such as from VP16 and the DNA binding, hinge and ligand binding domains from *Drosophila melanogaster* ecdysone receptor. Also contemplated for use in the chimeric receptor is the DNA binding, hinge and ligand binding domains from *Manduca Sexta* and *Chironomus tentans* (see e.g. 0198).

Claim 21 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Albertsen et al, US 6,504,082 B1 see entire document. **This is a new rejection.**

Albertsen et al teach chimeric receptor proteins in which one or more of the ligand binding, DNA binding or transactivation domains are obtained from a heterologous source from the domains present in the chimeric receptor (see e.g. column 4, line 38-43). The receptors are

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expressed in expression vectors driven by a promoter (see e.g. column 15, line 47-66). Cells transformed with the vectors are grown for the generation of transgenic plants and seeds (see e.g. column 20, line 51-62). In the chimeric receptors taught, the transactivation domain and DNA binding domains of *Ostrinia nubilalis* are replaced with that of VP16 or C1 transactivation domain and Gal4 (see e.g. column 23, line 19-28).

Conclusion

Claims 8, 9, 13, 14, 21, 23, 28 and 29 are rejected.

Claims 2-7, 10-12, 15-17, 22, 24-27, 50, 51, 58, 59, 66 and 67 are allowed.

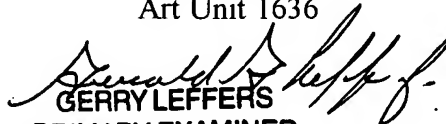
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (571)-272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
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October 11, 2004


GERRY LEFFERS
PRIMARY EXAMINER